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(21) International Application Number: PCT/US00/12407 (22) International Filing Date: 08 May 2000 (08.05.2000) (30) Priority Data: 60/133,032 07 May 1999 (07.05.1999) US 60/133,033 07 May 1999 (07.05.1999) US (60) Parent Application or Grant UNIVERSITY OF VIRGINIA PATENT FOUNDATION [/]; O. HELM, Gregory, A. [/]; O. KALLMES, David, F. [/]; O. HANKINS, Gerald, R. [/]; O. JENSEN, Mary, E. [/]; O. HELM, Gregory, A. [/]; O. KALLMES, David, F. [/]; O. HANKINS, Gerald, R. [/]; O. JENSEN, Mary, E. [/]; O. GARRETT, Arthur, S. ; O.	Published	
(54) Title: METHOD AND SYSTEM FOR FUSING A SPINAL REGION (54) Titre: TECHNIQUE ET SYSTEME PERMETTANT DE SOUDER UNE REGION DE L'EPINE DORSALE		
(57) Abstract <p>A method and system for fusing a region in the spine involve the use of at least one guide tube (10a) to pass instruments and substances into the spinal region in a minimally invasive manner. In the preferred practice of the method, a guide tube is anchored to a vertebra and the guide tube is moved to thereby position the vertebra. A steerable drilling tool (20a) is passed through the guide tube and steered into position to abrade at least a portion of an intervertebral disc, thereby creating a cavity in the disc. A flowing substance is passed into the cavity and permitted to solidify to establish fusion in the cavity. Optionally, an uninflated balloon (40) is inserted into the cavity and the balloon is filled with the flowing substance to contain the flowing substance.</p> <p>(57) Abrégé</p> <p>Dans le cadre de cette technique et avec le système correspondant permettant de souder une région de l'épine dorsale, il est utilisé au moins un tube guide (10a) pour faire passer des instruments et des substances dans la région vertébrale de la façon la moins effractive possible. Dans le mode de réalisation préféré de cette invention, un tube guide est ancré à une vertèbre et il est déplacé afin de positionner la vertèbre. Un instrument à percer orientable (20a) passe par le tube et est orienté de manière à lui faire prendre une position lui permettant d'abréger au moins une partie d'un disque intervertébral et, partant, de ménager une cavité dans ce disque. On introduit dans la cavité une substance fluide que l'on laisse solidifier afin de constituer une soudure dans la cavité. On introduit, éventuellement, un ballonnet non gonflé (40) dans la cavité et on le remplit de substance fluide.</p>		

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(57) Abstract			
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Description

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METHOD AND SYSTEM FOR FUSING A SPINAL REGION

10 This application relies on the benefit of priority of U.S. provisional patent application Serial No. 60/133,032 and U.S. provisional patent application Serial No. 60/133,033, both filed on May 7, 1999. These two applications are incorporated herein by reference.

15
BACKGROUND OF THE INVENTIONField of the Invention

20 The present invention relates to a method and system for fusing a spinal region. More particularly, the present invention relates to minimally invasive intravertebral disc distraction, rotation, or translation, removal of disc and/or vertebral bone material, and subsequent fusion of a disc.

25
Description of Related Art

30 There are five movable vertebrae in the lower back. This area is called the lumbar spine and is the flexible part of the back. Above the lumbar spine is the thoracic spine and below it is the sacrum and coccyx. Between each vertebra is a cushion referred to as an intervertebral disc. Each disc has a tough exterior rim of fibrous cartilage (similar to that of a radial tire), referred to as the annulus fibrosis. Within each disc is a resilient and "jelly-like" interior filling, referred to as the nucleus pulposus. The top and bottom of the disc are covered by relatively bony endplates.

40 Fig. 1 is a partial cross-section view of a portion of the spine. As shown in this figure, an intervertebral disc D is positioned between adjacent vertebral bodies V1 and V2 and includes an annulus fibrosis A, a nucleus pulposus N, and end plates EP.

5 Positioned on the vertebral bodies V1 and V2 are a superior articular process SAP, a
pedicle P, an inferior articular process IAP, a spinal process SP, and a facet joint FJ.

10 Each disc and the vertebra above and below it compromise a motion segment.
Movement such as bending forward (flexion) bending backwards (extension) and
twisting and turning (rotation) occur at these motion segments.

15 Approximately 80% of the American population experiences various forms of
lower back pain at some point during their lifetimes. Back pain is sometimes associated
with intervertebral disc trauma, degeneration of the disc or joints in the spine, disc
20 herniation, spinal instability, bone spurs, or inflamed ligaments. Back pain can also be
caused by an injury, disease, malalignment, tumor, hereditary weakness, and previous
back surgery. In addition, back and/or leg pain may be caused by pressure on the
25 spinal cord or on a spinal nerve. Techniques for treatment vary from simple
interventions such as rest and physical therapy to more complicated surgical
procedures such as spinal fusions. (As used herein the term "fusion" refers in general
30 to increasing the stability of a region of the spine, and does not necessarily require the
physical joining of portions of the spine.) Some surgical techniques have improved to
35 the point where invasiveness and trauma to non-spinal tissues can be kept to a
minimum.

40 Intervertebral discs commonly wear and tear, weakening their outer fibrous
structure. Increasing pressure in the spine may bulge and even rupture the disc,
causing back or leg pain. In normal aging, discs lose water and decrease their ability to
45 function as "shock absorbers." Narrowing discs increase stress to the facet joints.

5 Instability or abnormal motion may occur in the advanced stages of arthritis or
from trauma. Spondylolithesis is a forward slipping of one vertebra over another and
may result of severe instability. Spinal stenosis, a narrowing of the spinal canal, may
10 be a result of arthritis, putting pressure on the nerves or the spinal cord. Osteoarthritis
may result in narrowing of the disc spaces and development of bone spurs on the
vertebral bodies.

15 Hemiated discs are another form of injury to the intravertebral disc and are often
referred to as "slipped discs." This term is derived from the action of the nucleus tissue
when it is forced from the center of the disc. The disc itself does not slip. However, the
20 nucleus tissues located in the center of the disc can be placed under so much pressure
that it can cause the annulus to be hemiated or rupture against one or more of the
spinal nerves which can cause pain, numbness, or weakness in the lower back, leg or
25 foot. Other names used for hemiated discs are "prolapsed," "bulging," or "ruptured."
Depending on the results of a physical examination and the severity of the condition,
physicians commonly offer one of two forms of treatment. The first common treatment
30 is "conservative therapy," comprising bed rest, pain medication, and physiotherapy.

35 If conservative therapy does not bring enough pain relief, surgical procedures
are typically considered. The most common reason for recommending lower back
40 surgery is to relieve either back or leg pain. To decrease leg pain, pressure is removed
from the affected spinal nerve. Removal of a tumor, treatment of a fractured spine, and
repair of malalignments are other reasons surgery is undertaken. In order to
45 accomplish these objectives, the spine surgeon may remove the disc (discectomy) or a

5 part of the lamina (laminotomy) or remove the whole lamina (laminectomy). The
procedure is also referred to as a decompression because the pressure on the nerve or
the spinal cord or cauda equina is removed.

10 Sometimes motion between the vertebral bodies must also be stopped in an
effort to relieve pain. In such cases, the surgeon may elect to perform a spinal fusion
procedure. This procedure entails implanting pieces of bone graft, usually obtained
15 from the patient's own iliac crest bone (hip). The bone graft is intended to encourage
bone growth between the vertebral bodies and the posterior aspect of the spine. If the
bone develops and grows between the vertebrae, then the spine segment is said to
20 have "fused," and the motion between the vertebral bodies is therefore eliminated.

25 Fusion is best accomplished when the vertebrae are kept as motionless as
possible during the healing process which is usually four to six months. Physicians may
recommend achieving stability through additional internal fixation devices attached to
the vertebral bodies during the surgical procedure. This may be performed with a
30 combination of screws inserted meticulously into the vertebral body and attached to one
another with a series of rods, plates, wires, or hooks.

35 Until a few years ago, the only surgical treatment for herniated lumbar discs was
the open removal of a part of the herniated disc, an often effective but major operation
40 that requires general anesthesia, the dissection of muscle, removal of bone, and at
times, bone fusion. These procedures increase the risk to the patient of post-operative
45 complications.

5 In recent years, techniques employing the use of endoscopy have been
incorporated into lumbar spine surgery making minimally invasive spine surgery
possible while overcoming disadvantages of traditional techniques. Endoscopic
10 discectomy can provide an effective way to decompress and repair damaged discs
without open surgery. An endoscope provides clear visualization and magnification of
deep structures. First used in knee surgery, endoscopy (arthroscopy), with its
15 advanced miniaturization and video imaging technology, has made it possible for a less
invasive and less traumatic discectomy procedure for some disc patients.

20 Endoscopic discectomy is an outpatient surgical procedure to remove herniated
disc material. Using local anesthesia with the help of x-ray fluoroscopy and magnified
video for guidance, a small specially-designed endoscopic probe is inserted through the
25 skin of the back, between the vertebrae, and into the herniated disc space. Tiny
surgical attachments are then sent down the hollow center of the probe to remove a
portion of the offending disc. The microsurgical attachments can also sometimes be
30 used to push the bulging disc back into place and for the removal of disc fragments and
small bony spurs.

35 Endoscopic discectomy is different from open lumbar disc surgery because there
is no traumatic back muscle dissection, bone removal, or large skin incision. The risk of
40 complications from scarring, blood loss, infection, and anesthesia that may occur with
conventional surgery are drastically reduced or eliminated with this procedure.
Endoscopic discectomy was invented to be an effective treatment for herniated discs
45 while avoiding these risks.

5 A wide variety of spinal implants are available to the clinician for the surgical
treatment of spinal disorders. Most of the implants are designed to promote long term
fusion. For certain conditions, anterior fusion of the lumbar spine is a standard
10 operation. Despite improvements in fusion techniques and reductions in the
pseudoarthritis rate, improved procedures and devices are needed. Surgeons
specializing in operations on the vertebral column necessarily incorporate laparoscopic
15 surgery. Other concepts such as the biological enhancement of spinal fusion and
alternatives to fusion such as artificial discs and interbody cage devices are the object
of intense, multidisciplinary study. Despite these improvements, currently there are
20 neither devices designed to distract the intervertebral disc percutaneously nor minimally
invasive procedures to achieve spinal fusions.

25 In light of the foregoing, there is a need in the art for improving procedures and
devices associated with performing spinal surgery.

30 SUMMARY OF THE INVENTION

Accordingly, the present invention is directed to a method and apparatus that
35 substantially obviate one or more of the limitations of the related art. To achieve these
and other advantages and in accordance with the purposes of the invention, as
embodied and broadly described herein, the invention includes a method of fusing a
40 spinal region. In the method, a guide tube is contacted against at least one vertebra,
and a steerable drilling tool is inserted through the guide tube. The steerable drilling
45 tool is steered toward a disc and at least a portion of the end plates of the disc are

5 abraded with the drilling tool. At least the abraded end plates of the disc and a nucleus
of the disc are removed to form a cavity extending in at least the disc. A flowable fusion
substance is passed into the cavity. The fusion substance solidifies to provide fusion in
10 the cavity.

 In one aspect of the invention, the method includes inserting an inflatable implant
15 in the cavity, and the flowing of the flowable fusion substance includes passing the
fusion substance into the inflatable implant to inflate the implant in the cavity.

 In another aspect, the method includes inserting a balloon into the cavity,
20 inflating the balloon with a contrast agent, and viewing the balloon with imaging
equipment to evaluate the cavity. The balloon is then optionally removed or used to
contain the flowable infusion substance.
25

 In a further aspect, the guide tube and/or the drilling tool has a tracking element,
and a location of the guide tube and/or drilling element is determined relative to a
30 known reference point with a computer-controlled surgical navigation system.

 In the preferred practice of the invention, at least an annular portion of the
annulus fibrosis of the disc remains intact throughout the procedure. In addition, the
35 method preferably involves abrading material in the medullary area of the vertebra.

 Another aspect of the invention involves a method wherein a guide tube is
40 releasably anchored in at least one vertebra. There are various releasable anchoring
structures that could be provided on the guide tube. In the preferred embodiment, an
insertion end of the guide tube includes at least one thread permitting threading of the
45 guide tube in the at least one vertebra.

5 In still another aspect, the guide tube is moved when the guide tube is anchored
in the vertebra to thereby position the vertebra. The movement of the guide tube could
include distracting the vertebra away from the disc and/or rotating the vertebra.
10 Preferably, the location of the guide tube is determined with a computer controlled
surgical navigation system.

15 In yet another aspect, the method includes releasably anchoring a first guide
tube in a first vertebra, releasably anchoring a second guide tube in a second vertebra,
and moving at least one of the first and second guide tubes to thereby position the first
20 and second vertebrae with respect to one another.

An even further aspect involves a method wherein a balloon is inserted into a
cavity extending in at least a disc. The balloon is inflated with a contrast agent and
25 viewed with imaging equipment to evaluate the cavity. The contrast agent is then
preferably removed from the balloon, and a flowable fusion substance is flowed into the
cavity. Optionally, the balloon could be an inflatable implant which is inflated with the
30 fusion substance. Alternatively, the balloon could be removed from the cavity and an
inflatable implant could be placed in the cavity and filled with the fusion substance.

35 According to another aspect of the invention, at least a portion of a disc is
abraded with a steerable drilling tool, and disc material is removed to form a cavity. An
40 implant is placed in the cavity to provide fusion in the cavity. Preferably, the implant is
an inflatable balloon.

45 One more aspect of the invention involves a system for use in a spinal fusion
procedure. The system includes a steerable drilling tool having a rotatable bit

5 configured to abrade at least one of vertebral material and disc material, and at least
one guide tube having a proximal end portion, a distal end portion, and at least one
10 lumen extending from the proximal end to the distal end, the lumen being configured to
allow for passage of the steerable drilling tool therethrough. In addition, the system
could include one or more inflatable balloon implants.

15 A further aspect of the invention involves the steerable drilling tool alone. In one
embodiment, the steerable drilling tool includes a tubular member having at least one
axially movable steering element. Axial movement of the steering element varies
20 position of a distal insertion end of the tubular member with respect to a remainder of
the tubular member. The drilling tool could further include a flexible, rotatable drive
member in the tubular member and a drill bit at a distal insertion end of the drive
25 member. Rotation of the drive member rotates the drill bit. Optionally, the drilling tool
also includes a tracking element configured to interact with a computer-controlled
30 surgical navigation system to determine the location of a drill bit relative to a known
reference point.

35 It is to be understood that both the foregoing general description and the
following detailed description are exemplary, and are intended to provide further
explanation of the invention as claimed.

40 BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings are included to provide a further understanding of
45 the invention and are incorporated in and constitute a part of this specification. The

5 drawings illustrate embodiments of the invention and, together with the description,
serve to explain the principles of the invention. In the drawings,

Fig. 1 is a partial cross-section, lateral view of a portion of the spine;

10 Fig. 2 is a side view of a guide tube in accordance with an embodiment of a
system of the present invention;

Fig. 3 is a side view of a steerable drilling tool of the system embodiment;

15 Fig. 4 is a view similar to that of Fig. 1 showing an initial step in one preferred
procedure according to the present invention wherein guide tubes are inserted into the
pedicles of adjacent vertebrae;

20 Fig. 5 is a view similar to that of Fig. 4 showing movement of the guide tubes to
position the vertebrae;

25 Fig. 6 is a view similar to that of Fig. 5 showing a pair of steerable drilling tools
each passing through a respective one of the guide tubes;

30 Fig. 7 is a view similar to Fig. 6 showing advancement of the steerable drilling
tools to abrade vertebral material;

35 Fig. 8 is a view similar to Fig. 7 showing steering of the drilling tools and further
abrasion of vertebral material;

40 Fig. 9 is view similar to Fig. 8 showing a cavity created as a result of abrasion
with the drilling tools;

45 Fig. 10 is a view similar to Fig. 9 showing initial insertion of a balloon implant in
the cavity;

5 Fig. 11 is a view similar to Fig. 10 showing the balloon implant in an inflated state;

10 Fig. 12 is a view similar to Fig. 11 showing the balloon implant after removal of the the guide tubes;

15 Fig. 13 is a view of an alternate embodiment of a balloon implant that is configured to extend along a cavity passing through a pair of adjacent discs;

 Fig. 14 is a view of an alternative procedure according to the present invention wherein a single guide tube is used to remove intervertebral disc material;

20 Fig. 15 is a view similar to Fig. 14 showing insertion of a balloon implant in a cavity formed at least partially in the disc;

25 Fig. 16 is a view similar to Fig. 15 showing the balloon implant in an inflated state filling the cavity; and

30 Fig. 17 is a view similar to Fig. 16 showing the balloon implant in place after removing the guide tube.

35 DESCRIPTION OF THE PREFERRED EMBODIMENTS

 Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings.

40 Wherever possible, the same reference numbers (optionally including different suffixes) are used in the drawings and the description to refer to the same or like parts.

45 Figs. 2, 3, 5, and 10 show examples of components that could be included in an embodiment of a system according to the present invention. As shown in Fig. 2, the

5 system preferably includes at least one guide tube 10 having at least one inner lumen
extending from a proximal end portion to a distal end portion. The distal end portion of
the guide tube 10 preferably includes a releasable anchoring element 12 for releasably
10 anchoring the distal end portion of the guide tube 10 in at least one vertebra. In the
embodiment shown in Fig. 2, the anchoring element 12 is at least one thread on an
outer surface of the guide tube 10. The thread permits the guide tube 10 to be
15 removably threaded into a hole bored in a vertebra.

The guide tube 10 is preferably made of stainless, surgical steel but may be
20 made of metal composites, ceramic composites, surgical polymers or surgical plastics.

Preferably, the guide tube 10 includes a suitable tracking element 14 configured
to interact with a computer controlled surgical navigation system (not shown) using a
25 detector for determining the position of the guide tube 10 with respect to a known
reference in 3D space. By way of example only, the tracking element 14 could be at
least one LED emitter/reflector located on a proximal end portion of the guide tube 10.
30 The tracking element 14 could also be any structure that is capable of being
detected/tracked by means of a surgical navigation system that uses any sonic, optical,
35 electromagnetic, or other suitable technology known in the art. For example, the
tracking element 14 is particularly capable of being used with a surgical navigation
system constructed according to the teachings of U.S. Patent No. 5,383,454; PCT
40 Application No. PCT/US94/04530 (Publication No. WO 94/24933); and/or PCT
Application No. PCT/US95/12894 (Publication No. WO 96/11624), the disclosures of
45 which are incorporated by reference.

5 The guide tube 10 includes a lumen that extends from its proximal end portion to
its distal end portion. Preferably, the lumen is sized to allow for passage therethrough
of at least one tool, such as the drilling tool 20 shown in Fig. 3. The drilling tool 20
10 preferably includes a bit 22 (i.e., burr) configured to abrade soft tissue or bone, such as
portions of an intervertebral disc or a vertebra. The bit 22 is preferably a high speed
15 drill bit made of hardened surgical, stainless steel and optionally coated with Teflon or
other coatings to prevent aggregation or sticking of osseous material. The bit 22 is
coupled to a flexible, rotatable drive member 24, such as a cable, that is rotatably
20 driven by an external motor (not shown) to rotate the bit 22. The drive member 24
passes through a tubular member 26 that is preferably configured to be steerable.

25 As shown in Fig. 3, the tubular member 26 includes a number of segments 28a-
28e. Hinge members 30a, 30b, 30c and 30d couple adjacent pairs of the segments
28a-28b, 28b-28c, 28c-28d, 28d-28e together to permit relative pivotal movement of the
30 segments in each of the pairs. An axially movable steering element 32, such as a
cable, passes freely through the segments 28b-28e and has a distal end connected to
the distal segment 28a. Axial movement of the steering element 32 causes bending at
35 one or more of the hinge members 30a-30d in a plane to vary the position of the distal
end portion of the tubular member 26 with respect to the remainder of the tubular
member 26. This enables steerable movement of the drilling tool 20, especially when
40 the movement at the distal end portion is combined with rotation of the tubular member
26 and/or axial movement of the tubular member 26. Of course, there are many
45 different ways in which the drilling tool 20 could be constructed to provide steering.

5 A tracking element 34 could be provided on the drilling tool 20 to interact with a
computer controlled surgical navigation system to determine the location of the bit 22
with respect to a known reference point. For example, the tracking element 34 could be
10 provided on the steering element 32 and constructed like the tracking element 14
shown in Fig. 2.

15 The drilling tool 20 is preferably made of surgical steel, but the drive member 24
and steering element 32 could be made of metal composites, surgical polymers, or
other suitable materials. Preferably, at least a portion of the drilling tool 20 is capable of
20 being imaged with fluoroscopic imaging. The drilling tool 20 could be constructed to be
connected to a stereotactic device that could be used to determine the position of the
bit 22.

25 Structure could be provided on the drilling tool 20 to remove materials with
suction. For example, the drilling tool could include a lumen capable of being coupled
30 to a suction source. For example, a flexible tube, such as surgical polymer tubing,
could be provided in the tubular member and have an open end extending adjacent to
the bit 22.

35 Although the steerable drilling tool 20 is described below as being used in a
spinal fusion procedure, the drilling tool 20 could be used in a number of different spinal
40 or non-spinal procedures.

The system according to the invention also preferably includes at least one
45 inflatable balloon implant 40 shown in Figs. 10-12. The balloon implant 40 is configured
to be filled with material to provide fusion in a cavity that is formed at least partially in an

5 intervertebral disc, as described below. The balloon implant 40 is preferably made of a
biodegradable substance such as collagen. The balloon implant 40 and the material
used to fill it may include growth factors, such as bone morphogenic proteins or
10 fibroblast growth factor, genetically modified cells for replacement therapy, or
mesenchymal stem cells to further promote bony fusion.

15 The system according to the present invention could include other components,
such as a device for providing suction and/or irrigation of a surgical site. Preferably, all
or some of the components are made of permanent or disposable materials that are
20 capable of being sterilized.

The present invention also includes one or more preferred methods of fusing a
25 spinal region. These procedures are explained with reference to the structural
embodiments described above. However, it should be understood that the method of
the invention could be practiced with structure other than that disclosed herein. In
30 addition, the structure of the present invention could be used with processes other than
those described herein.

35 In one method according to the present invention, a patient is placed on an
appropriate operating surface. Optionally, imaging equipment, such as fluoroscopy, is
used to visualize a region of the spine. Small stab incisions are made in the back and a
40 conventional drill is preferably used to drill a hole through corticle material on the outer
surface of the pedicle of a vertebra.

45 For the procedure shown in Fig. 4, a first hole is drilled in the pedicle of a first
vertebra and a second hole is drilled in a pedicle of a second vertebra adjacent to the

5 first vertebra. Although Figs. 4-11 show these holes as being substantially parallel to
the plane of the disc, the holes are preferably angled from about 30 degrees to about
10 45 degrees with respect to the plane of the disc so that the axes of the holes form an
angle having a vertex at the disc.

A respective guide tube 10a, 10b is placed in contact with each of the vertebrae.
15 Preferably, each guide tube 10a, 10b is releasably anchored in the corresponding
pedicle hole by engaging the threads on the guide tube 10a, 10b in the vertebrae.
Once the guide tubes 10a and 10b have been inserted, an X-ray, CT scan or other
20 diagnostic scan could be used to localize the anatomical position of the tubes 10a and
10b, identify the best position for fusion and identify the best insertion points for
subsequent instrumentation.

25 After anchoring the guide tubes 10a and 10b, at least one of the guide tubes 10a
and 10b is moved to thereby position one or more of the vertebrae. For example, as
30 shown in Fig. 5, a distraction tool 50 is coupled to the guide tubes 10a and 10b to force
the guide tubes 10a and 10b apart from one another and thereby distract one or more
of the vertebrae away from the disc. The distraction tool 50 could be constructed in
35 many different ways. For example, this device could have a ratchet adjustment.

In addition to moving the guide tubes 10a, 10b toward or away from each other,
40 one or more of the anchored guide tubes 10a, 10b could be rotated (or translated) to
thereby rotate (or translate) one or more of the vertebrae. Preferably, a computer-
controlled surgical navigation device is used to determine the movement of the guide
45

5 tubes, for example, by interacting with the tracking element 14 shown in Fig. 2. This preferably enables a surgeon to visualize the repositioning of the vertebrae.

10 One or more steerable drilling tools 20a and 20b are inserted through the guide tubes 10a and 10b. The drive member 24 (Fig. 3) of each drilling tool 20a, 20b is rotated to thereby rotate each bit 22. Each drilling tool is moved further through the
15 guide tubes 10a and 10b, as shown in Fig. 7, and the bit 22 abrades material in the respective vertebra, including medullary material spaced away from the disc. As shown in Fig. 8, each of the drilling tools 20a and 20b are preferably steered toward the disc,
20 for example by axially moving the steering element 32 (Fig. 3), and the drilling tools 20a and 20b abrade at least a portion of the end plates of the disc between the vertebrae.

25 The material abraded by the drilling tools 20a and 20b is preferably removed through one or both of the guide tubes 10a, 10b. For example, a suction and/or irrigation device could be passed into one of the tubes 10a and 10b, while one of the
30 drill tools is passed through the other of the tubes 10a and 10b.

35 The position of the distal end of the drilling tools 20a and 20b is preferably determined, for example, by using a computer controlled surgical navigation device that interacts with the tracking element 34 (Fig. 3). After abrasion of all material, the drilling tools 20a and 20b are pulled out of the tubes 10a and 10b, and the further removal of
40 any remaining loose material occurs via suction, irrigation, flexible forceps, or other means for clearing such loose material.

45 Eventually, all of the interior of the disc, including its nucleus, is removed to form a cavity extending through the disc and preferably into portions of the adjacent

5 vertebrae. Preferably, none of the circumferential segments of the annulus fibrosis are
abraded or removed during the procedure, such that at least a portion of the fibrosis
extends around the cavity.

10 In a preferred practice of the invention, the inflatable balloon implant 40 is
preferably inserted into the cavity via one of the guide tubes 10a and 10b. The balloon
15 is preferably filled with a contrast agent, as shown in Fig. 11, and the balloon is viewed
with appropriate imaging equipment, such as a fluoroscope. One possible imaging
agent that could be used to inflate the balloon is OMNIPAQUE. Since the inflated
20 balloon preferably fills the entire cavity, the imaging of the balloon can be used to
evaluate whether the cavity is properly configured. It can also be used to ascertain
proper anatomic alignment or position and to verify complete filling of the cavity. In the
25 event that further material needs to be removed to enlarge the cavity, the implant 40
could be removed from the cavity, and abrasion with one or more of the steerable
30 drilling tools could be continued.

When the cavity is properly formed, a flowable fusion substance is preferably
35 passed into the cavity via one of the guide tubes 10a, 10b. Preferably, the fusion
substance is a substance capable of solidifying such that it is no longer readily flowable.
For example, the fusion substance could be a solidifying agent including
40 polymethacrylate, such as methylmethacrylate or cranioplastic methacrylate,
hydroxyapatite, another polymer, and/or a biological matrix. The flowable substance
may include growth factors, such as bone morphogenic proteins or fibroblast growth
45 factor, genetically modified cells for replacement therapy or mesenchymal stem cells to

5 further promote bony fusion. In addition, the fusion substance could include antibiotics
such as tobramycin, for example.

10 In one possible practice of the invention, the balloon implant used for the
imaging is removed from the cavity before the fusion substance alone is passed into the
cavity. Alternatively, the balloon implant 40 used for the imaging could be drained of
15 the imaging agent and then filled with the fusion substance via one of the guide tubes
10a, 10b. In another alternate practice of the invention, the balloon implant 40 used for
the contrast agent is removed from the cavity and another balloon implant is inserted in
20 the cavity and filled with the fusion substance. Filling a balloon implant with the fusion
substance is preferred in order to contain the fusion substance and prevent migration
into unintended areas, such as the area near the spinal chord. After passing the fusion
25 substance into the cavity, the tubes 10a and 10b are removed from the vertebrae.

Fig. 12 shows the balloon implant 12 in place after being filled with the flowable
30 agent and after solidification of the fusion substance. Fig. 13 shows an alternate
embodiment of a balloon implant 40a that is configured to fill a relatively larger cavity
extending into two adjacent discs positioned near a spinal fracture.

35 In the preferred practice of the invention, the guide tubes 10a, 10b could be
moved at various times during the procedure to reposition one or more of the vertebrae.
For example, the movement shown in Fig. 5 could take place after the cavity is fully
40 formed. In addition, the vertebrae could be retained in their repositioned state until the
fusion substance solidifies.
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5 Figs. 14-17 show an alternative procedure like that shown in Figs. 4-13, but
involving a single guide tube 10. As shown in Fig. 14, the guide tube 10 is used to
remove the inner material from a disc with suction applied through the guide tube 10.
10 As shown in Figs. 15-17, a balloon is inserted into a cavity formed in the disc and
eventually filled with the fusion substance to fuse the spinal region.

15 The method and apparatus according to the invention could be used for
noninvasive or minimally invasive spinal disc distraction, rotation or translation and
subsequent stabilization. The invention could be used for treatment of spinal disorders
20 including, but not limited to, scoliosis, lordosis, kyphosis, spinal fractures, spinal
instability, tumors, spinal degeneration due to disease, disc bulges, herniations, and
tears. Preferably, the invention will stabilize the spine and correct anatomic
25 misalignment caused by the above disorders. For example, the movement of one or
more of the guide tubes to reposition one or more vertebrae could be used to correct
30 scoliosis prior to spinal fusion.

The method and apparatus according to the present invention could be used for
procedures in many different areas of the spine. Although the invention has particular
35 advantages in association with procedures for the lower spinal area, the invention could
also be used for procedures for the thoracic area or the cervical area, for example.

40 Preferably, the present invention shortens the time a patient is being operated on
by speeding up the repair of the spinal disorders and thereby reduces risks associated
with pre- and post-operative complications. The invention also preferably decreases
45 pain by decreasing pressure on nerve roots, improves mobility, and improves long-term

5 alignment of the spine, thereby providing improved outcomes for spinal disorder patients.

10 The invention could be used to fuse regions of various sizes. For example, the invention could be practiced to fuse two adjacent spinal discs or may be used across more than two.

15 There are a variety of different ways in which the various instruments could be guided during a procedure. For example, stereotactic guidance could be used.

20 It will be apparent to those skilled in the art that various modifications and variations can be made to the structure and methodology of the present invention without departing from the scope or spirit of the invention. In view of the foregoing, it is intended that the present invention cover modifications and variations of this invention
25 provided they fall within the scope of the following claims and their equivalents.

Claims

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WHAT IS CLAIMED IS:

1. A method of fusing a spinal region, the method comprising:

contacting a guide tube against at least one vertebra;

inserting a steerable drilling tool through the guide tube;

steering the steerable drilling tool toward a disc;

abrading at least a portion of the end plates of the disc with the drilling tool;

removing at least the abraded end plates of the disc and a nucleus of the disc to form a cavity extending in at least the disc; and

flowing a flowable fusion substance into the cavity, the fusion substance being configured to solidify to provide fusion in the cavity.

2. The method of claim 1, further comprising releasably anchoring the guide tube in the at least one vertebra.

3. The method of claim 2, wherein an insertion end of the guide tube includes at least one thread, and wherein the anchoring includes threading the insertion end of the guide tube in the at least one vertebra.

4. The method of claim 2, further comprising moving the guide tube when the guide tube is anchored in the vertebra to thereby position the vertebra.

5. The method of claim 4, wherein the movement of the guide tube includes at least one of distracting the vertebra away from the disc with a distraction tool and rotating the vertebra.

5 6. The method of claim 1, wherein the guide tube further includes at least
one tracking element, and wherein the method further comprises determining the
location of the guide tube relative to a known reference point with a computer controlled
10 surgical navigation system configured to interact with the tracking element.

 7. The method of claim 1, wherein the steerable drilling tool includes a
15 tubular member having at least one axially movable steering element, and wherein the
steering comprises axially moving the steering element to vary position of a distal
insertion end of the tubular member with respect to a remainder of the tubular member.

20 8. The method of claim 7, wherein the drilling tool further includes a flexible,
rotatable drive member in the tubular member and a drill bit at a distal insertion end of
the drive member, and wherein the abrading includes rotating the drive member to
25 rotate the drill bit.

 9. The method of claim 1, wherein the removing of the end plates and
30 nucleus includes removing disc material with at least one of suction and irrigation.

 10. The method of claim 1, further comprising inserting an inflatable implant in
the cavity, and wherein the flowing of the flowable fusion substance includes passing
35 the fusion substance into the inflatable implant to inflate the implant in the cavity.

 11. The method of claim 1, wherein the flowable substance includes a
40 solidifying agent comprising polymethacrylate.

 12. The method of claim 1, wherein the flowable substance includes material
45 for inducing bone growth.

5 13. The method of claim 12, wherein the bone growth inducing material is
chosen from morphogenic protein, fibroblast growth factor, genetically modified cells,
and stem cells.

10 14. The method of claim 1, wherein the method further comprises inserting a
balloon into the cavity, inflating the balloon with a contrast agent, and viewing the
balloon with imaging equipment to evaluate the cavity.

15 15. The method of claim 1, wherein the removing does not remove any
circumferential segment of the annulus fibrosis of the disc.

20 16. The method of claim 1, wherein the abrading includes abrading material in
the medullary area of the at least one vertebra.

25 17. The method of claim 16, wherein the disc is located between first and
second vertebrae and the cavity extends between the first and second vertebrae, and
wherein the method further comprises contacting a first guide tube against the first
vertebra and a second guide tube against the second vertebra, and wherein the
30 inserting includes inserting the drilling tool through at least one of the first and second
guide tubes and wherein the removing includes removing at least one of vertebra
35 material and disc material via at least one of the first and second tubes.

40 18. The method of claim 17, wherein the method further comprises releasably
anchoring the first guide tube in the first vertebra, releasably anchoring the second
guide tube in the second vertebra, and moving at least one of the first and second
guide tubes to thereby position the first and second vertebrae with respect to one
45 another.

5 19. The method of claim 18, wherein at least one of the first and second guide
tubes includes a tracking element and wherein the method further comprises
determining the location of said at least one guide tube relative to a known reference
10 point with a computer controlled surgical navigation system configured to interact with
the tracking element.

15 20. The method of claim 1, wherein the method includes determining the
location of a drill bit on the drilling tool by determining the location of the drill bit relative
to a known reference point with a computer controlled surgical navigation system.

20 21. A method of fusing a spinal region, the method comprising:
releasably anchoring a guide tube in at least one vertebra adjacent to a disc;
removing at least a nucleus of the disc to form a cavity extending in at least the
25 disc;
moving the guide tube when the guide tube is anchored in the vertebra to
30 thereby change position the vertebra; and
flowing a flowable fusion substance into the cavity, the fusion substance being
configured to solidify to provide fusion in the cavity.

35 22. The method of claim 21, wherein the movement of the guide tube includes
at least one of distracting the vertebra away from the disc with a distraction tool and
rotating the vertebra.

40 23. The method of claim 21, wherein the guide tube further includes at least
one tracking element, and wherein the method further comprises determining the
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5 location of the guide tube relative to a known reference point with a computer controlled surgical navigation system configured to interact with the tracking element.

10 24. The method of claim 21, further comprising inserting an inflatable implant in the cavity, and wherein the flowing of the flowable fusion substance includes passing the fusion substance into the inflatable implant to inflate the implant in the cavity.

15 25. The method of claim 21, wherein the removing does not remove any circumferential segment of the annulus fibrosis of the disc.

20 26. The method of claim 21, wherein the removing includes removing material from the medullary area of the at least one vertebra.

25 27. The method of claim 26, wherein the disc is located between first and second vertebrae and the cavity extends between the first and second vertebrae, and the method further comprises releasably anchoring a first guide tube in the first vertebra, releasably anchoring a second guide tube in the second vertebra, and
30 wherein the moving includes moving at least one of the first and second guide tubes to thereby position the first and second vertebrae with respect to one another.

35 28. The method of claim 18, wherein at least one of the first and second guide tubes includes a tracking element and wherein the method further comprises determining the location of said at least one guide tube relative to a known reference
40 point with a computer controlled surgical navigation system configured to interact with the tracking element.

45 29. A method of fusing a spinal region, the method comprising:

5 removing at least a nucleus of an intervertebral disc to form a cavity extending in
at least the disc;

inserting a balloon into the cavity;

10 inflating the balloon with a contrast agent;

viewing the balloon with imaging equipment to evaluate the cavity;

15 removing the contrast agent from the balloon; and

flowing a flowable fusion substance into the cavity, the fusion substance being
configured to solidify to provide fusion in the cavity.

20 30. The method of claim 29, wherein the balloon is an inflatable implant and
wherein the flowing includes passing the fusion substance into the inflatable implant to
inflate the implant in the cavity.

25 31. The method of claim 29, wherein the flowable substance includes a
solidifying agent comprising polymethacrylate.

30 32. The method of claim 29, wherein the flowable substance includes material
for inducing bone growth.

35 33. The method of claim 32, wherein the bone growth inducing material is
chosen from morphogenic protein, fibroblast growth factor, genetically modified cells,
and stem cells.

40 34. The method of claim 29, wherein the method further comprises removing
the balloon from the cavity prior to flowing the flowable substance into the cavity.

5 35. The method of claim 34, wherein the method further comprises inserting
an inflatable implant into the cavity and wherein the flowing includes passing the fusion
substance into the inflatable implant to inflate the implant in the cavity.

10 36. The method of claim 29, wherein the removing does not remove any
circumferential segment of the annulus fibrosis of the disc.

15 37. The method of claim 29, wherein the removing includes removing material
from the medullary area of at least one vertebra adjacent to the disc.

20 38. A method of fusing a spinal region, the method comprising:
contacting a guide tube against at least one vertebra;
inserting a steerable drilling tool through the guide tube;
steering the steerable drilling tool toward a disc;
25 abrading at least a portion of the disc with the drilling tool;
removing at least the abraded portion of the disc and a nucleus of the disc to
30 form a cavity extending in at least the disc; and
placing an implant in the cavity, the implant being configured to provide fusion in
the cavity.

35 39. The method of claim 38, wherein the implant is inflatable and wherein the
placing of the implant includes inserting the balloon in the cavity in an uninflated state
40 and inflating the balloon in the cavity.

45 40. The method of claim 38, wherein the abrading includes abrading vertebral
material in the medullary area of the at least one vertebra such that the cavity extends
into the at least one vertebra.

5 41. A system for use in a spinal procedure, the system comprising:

 a steerable drilling tool having a rotatable bit configured to abrade at least one of
vertebral material and disc material; and

10 at least one guide tube having a proximal end portion, a distal end portion, at
least one lumen extending from the proximal end portion to the distal end portion, the
lumen being configured to allow for passage of the steerable drilling tool therethrough.

15 42. The system of claim 41, wherein the distal end portion of the guide tube
includes at least one thread configured to permit releasable anchoring of the guide tube
in at least one vertebra.

20 43. The system of claim 41, wherein the guide tube further includes at least
one tracking element configured to interact with a computer controlled surgical
navigation system for determining the position of the guide tube with respect to a known
reference.

25 44. The system of claim 41, wherein the steerable drilling tool includes a
tubular member having at least one axially movable steering element, axial movement
of the steering element varying position of a distal insertion end of the tubular member
with respect to a remainder of the tubular member.

30 45. The system of claim 44, wherein the drilling tool further includes a flexible,
rotatable drive member in the tubular member and a drill bit at a distal insertion end of
the drive member, rotation of the drive member rotating the drill bit.

35 46. The system of claim 41, further comprising a tracking element on the
drilling tool, the tracking element being configured to interact with a computer controlled

5 surgical navigation system to determine the location of a drill bit on relative to a known
reference point.

10 47. The system of claim 41, further comprising a balloon implant configured to
be filled with material to provide fusion in a cavity formed at least in an intervertebral
disc.

15 48. The system of claim 47, wherein the balloon implant is made of a
biodegradable substance.

20 49. The system of claim 48, wherein the biodegradable substance includes
collagen.

25 50. The system of claim 47, wherein the balloon implant contains growth
factors.

51. The system of claim 47, wherein the balloon implant contains genetically
modified cells.

30 52. The system of claim 41, wherein the drilling tool further includes at least
one lumen for coupling to a suction source.

35 53. A steerable drilling tool comprising:
a flexible tubular body having a proximal end portion and a distal end portion;
a flexible, rotatable drive member in the tubular member;
40 a bit on the end of the rotatable drive member, the bit being rotated during
rotation of the drive member and being located at the distal end portion of the tubular
body; and

5 a steering element configured such that movement of the steering element varies
position of the distal end portion of the tubular member with respect to the remainder of
the tubular member.

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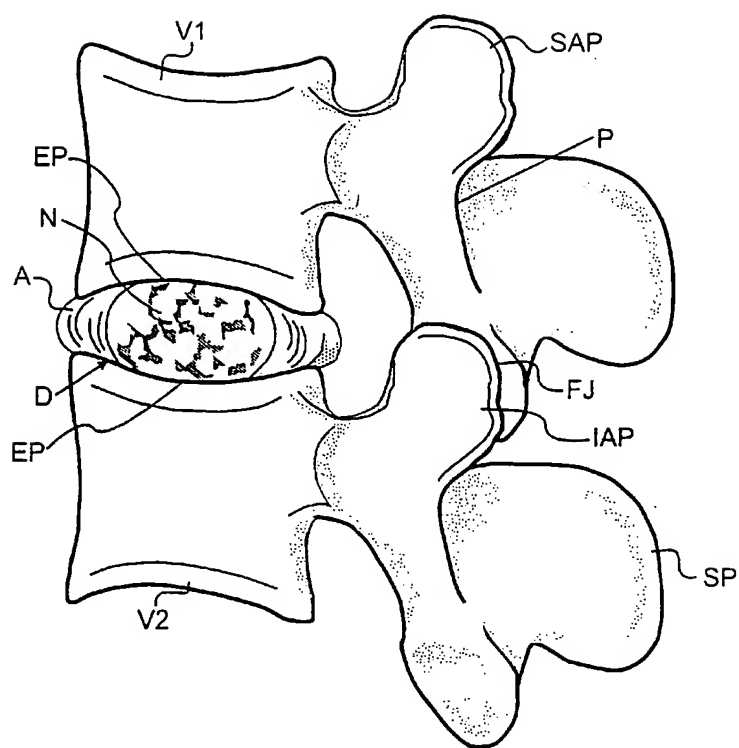


FIG. 1

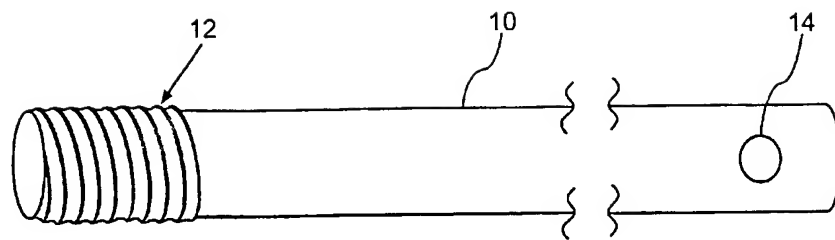


FIG. 2

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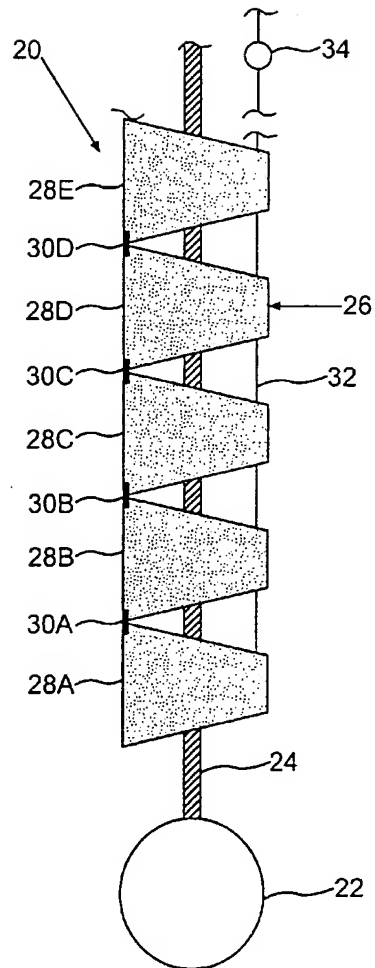


FIG. 3

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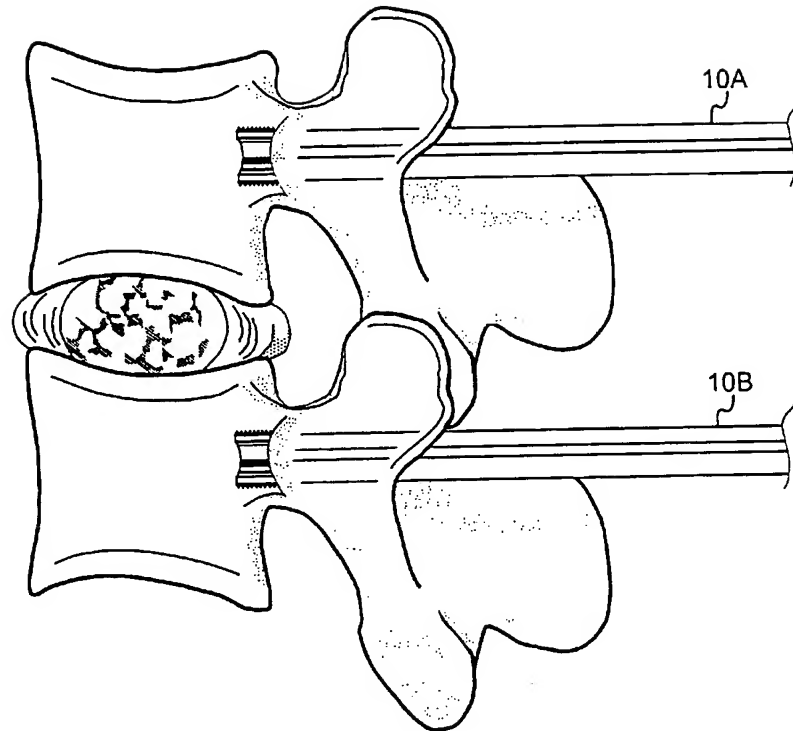


FIG. 4

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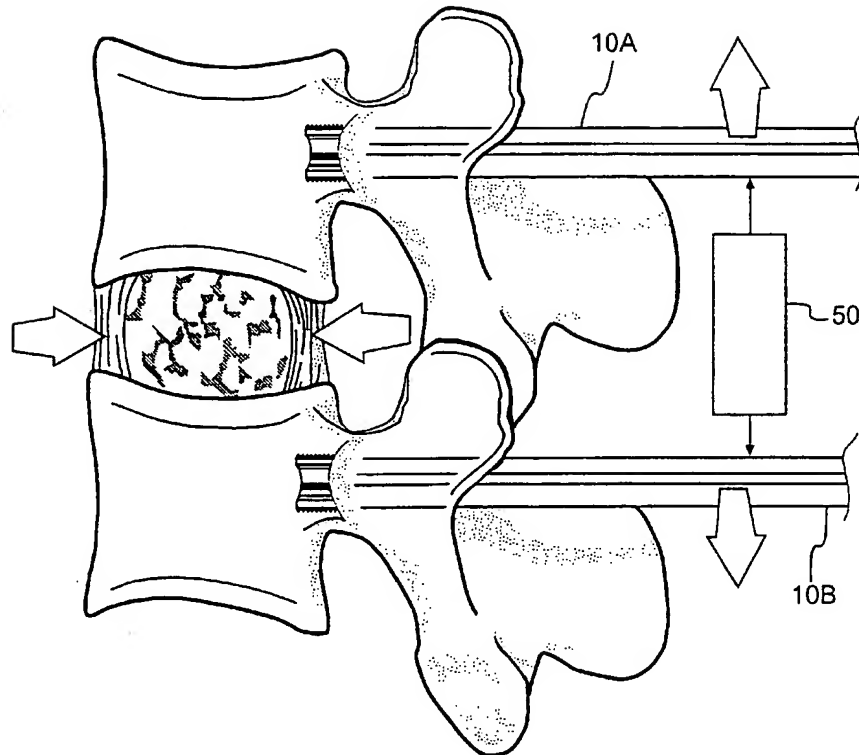


FIG. 5

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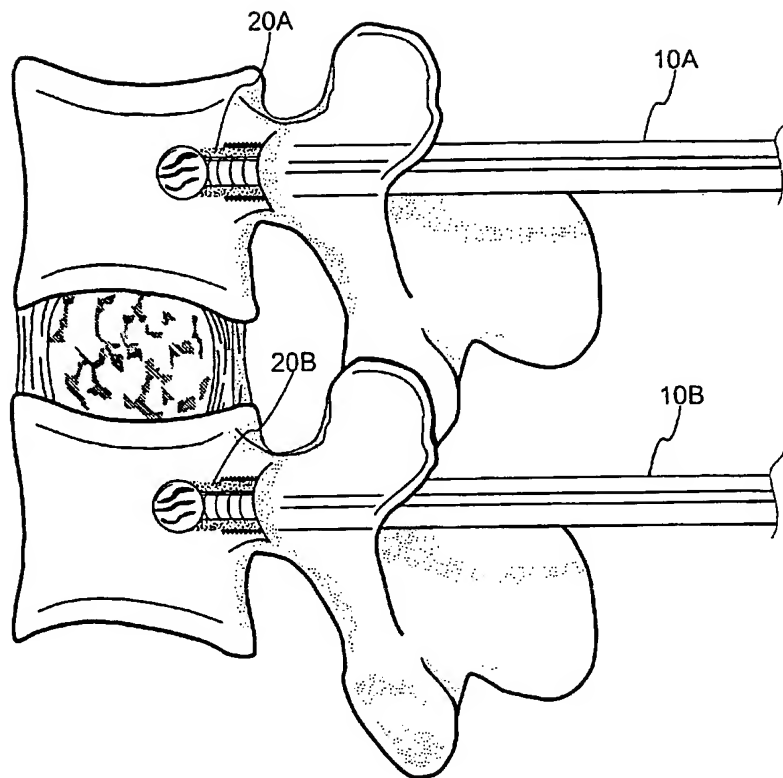


FIG. 6

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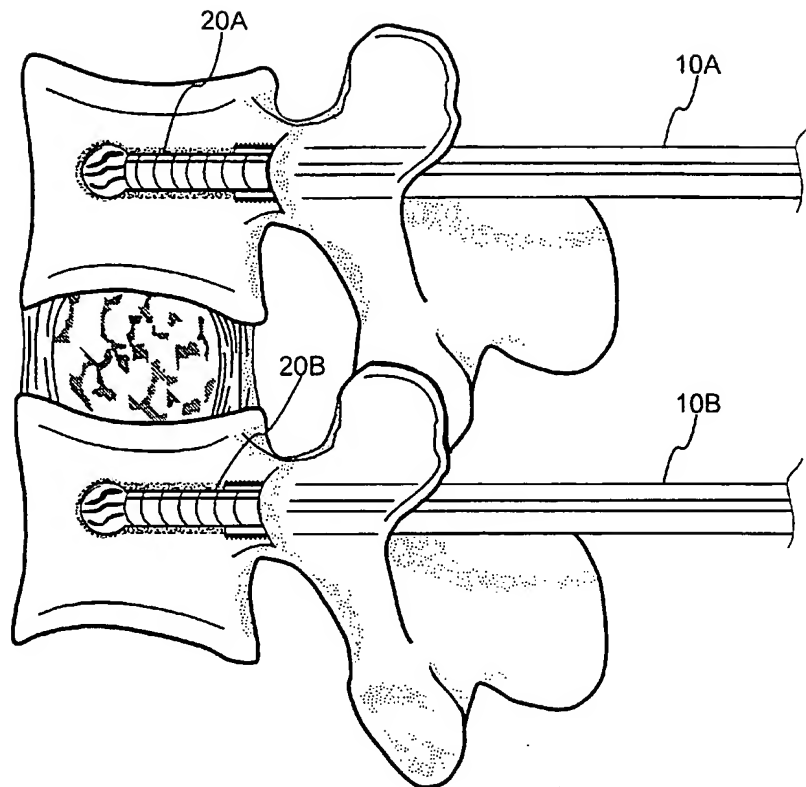


FIG. 7

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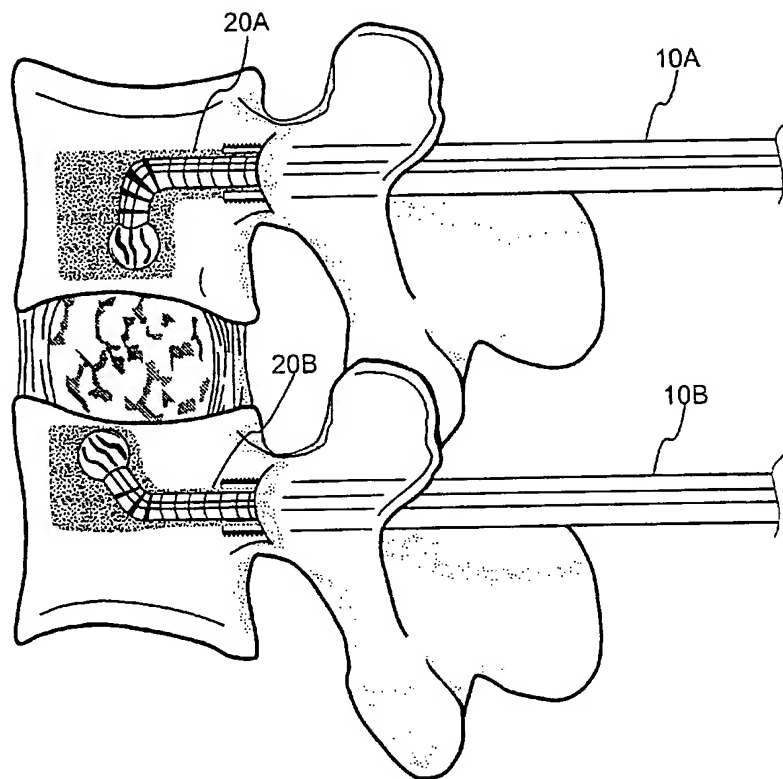


FIG. 8

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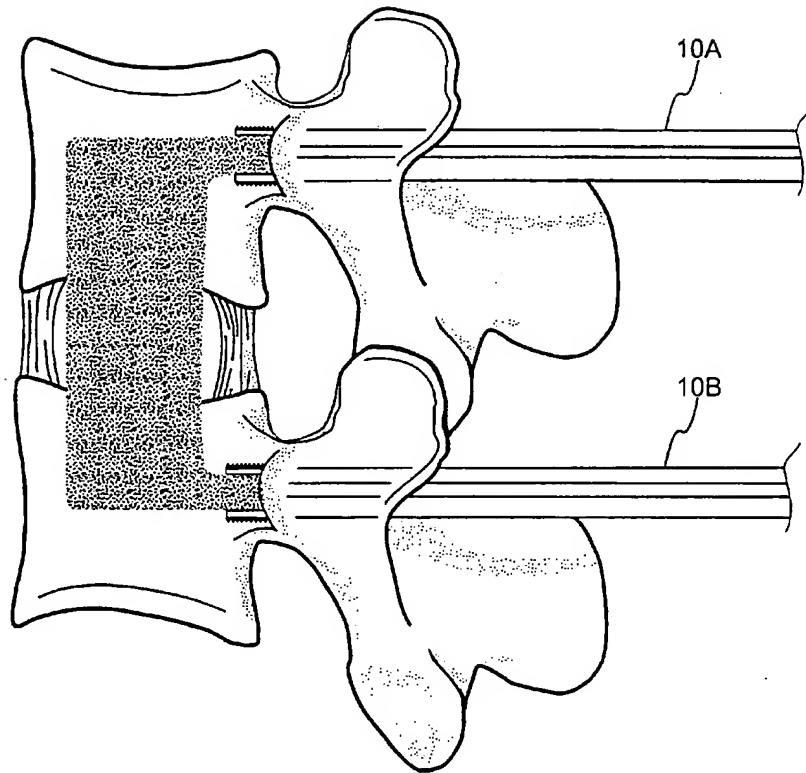


FIG. 9

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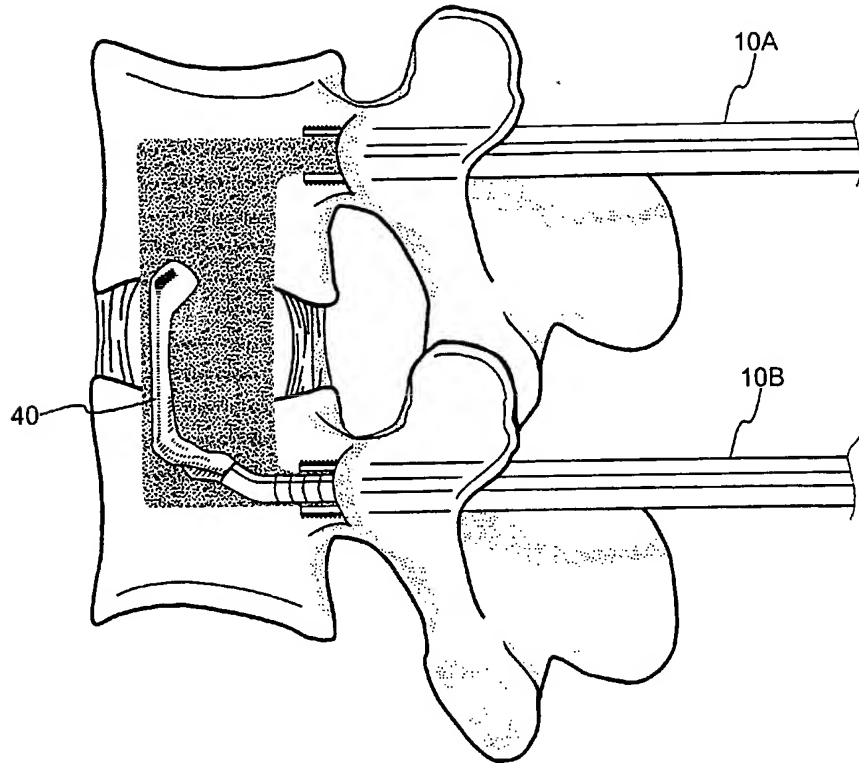


FIG. 10

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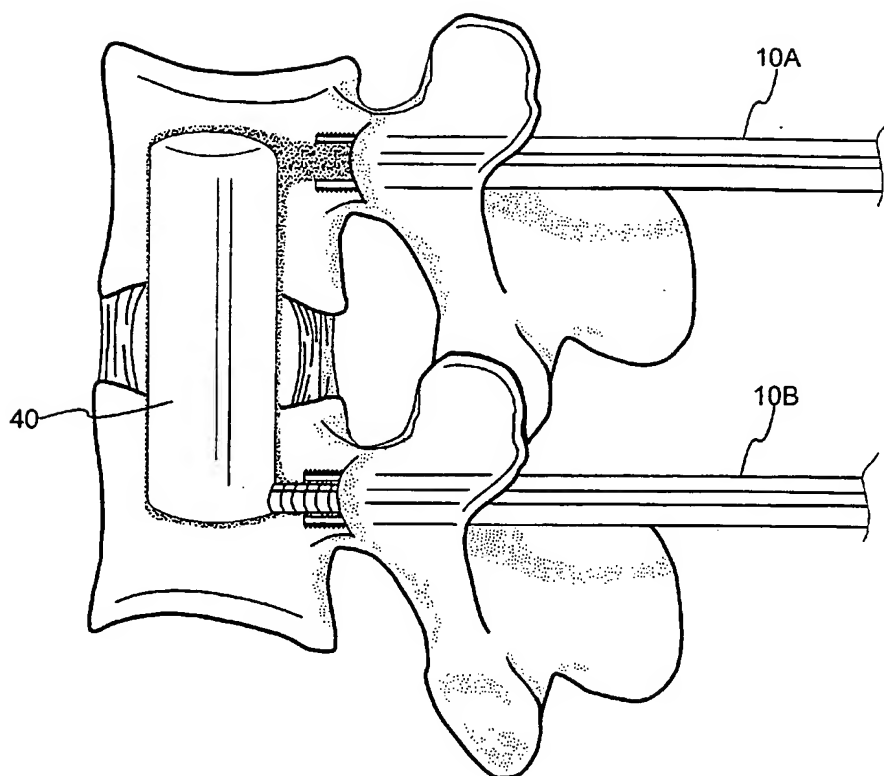


FIG. 11

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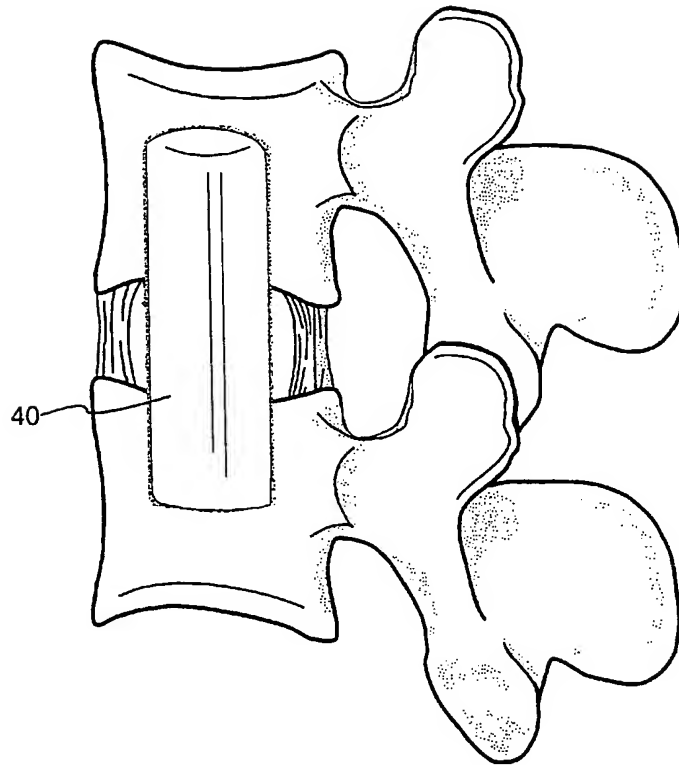


FIG. 12

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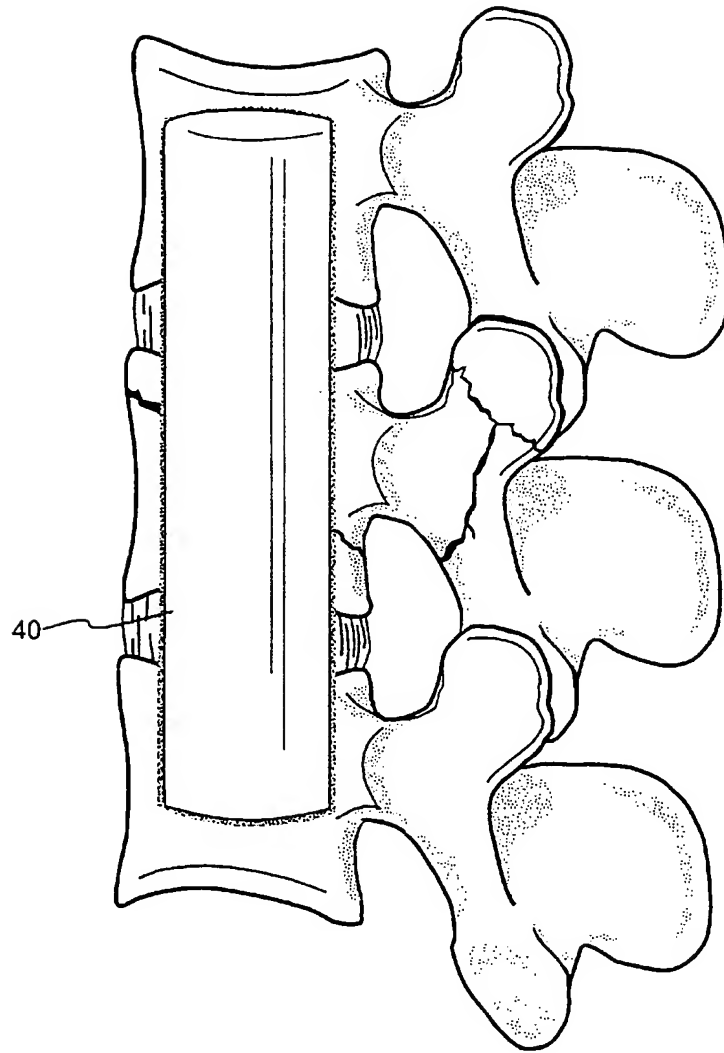


FIG. 13

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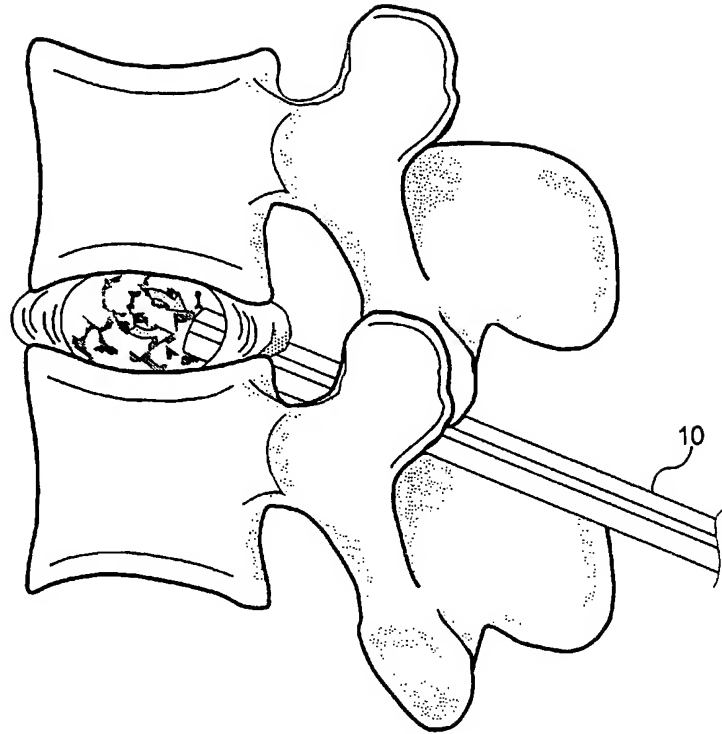


FIG. 14

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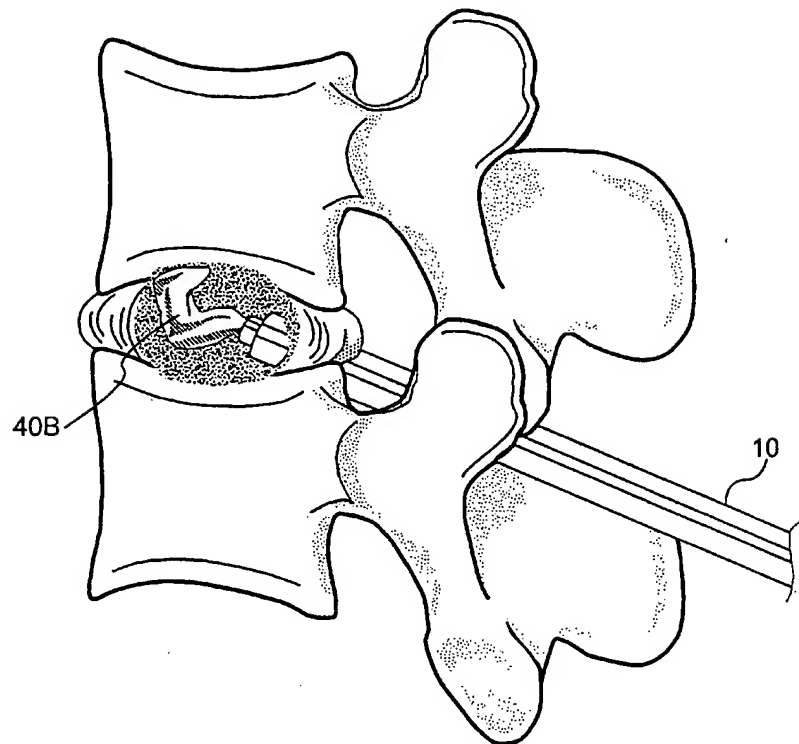


FIG. 15

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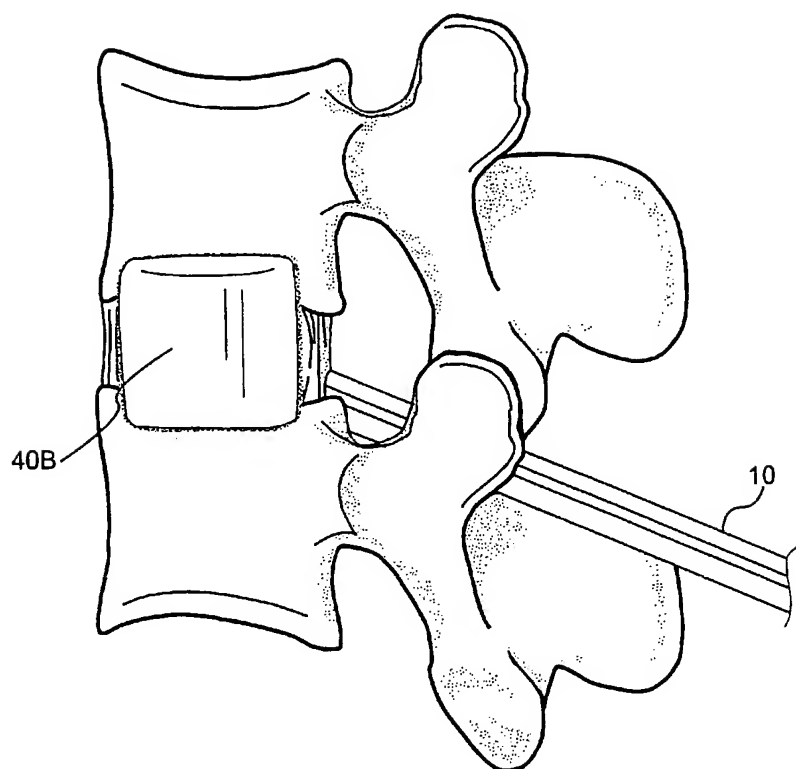


FIG. 16

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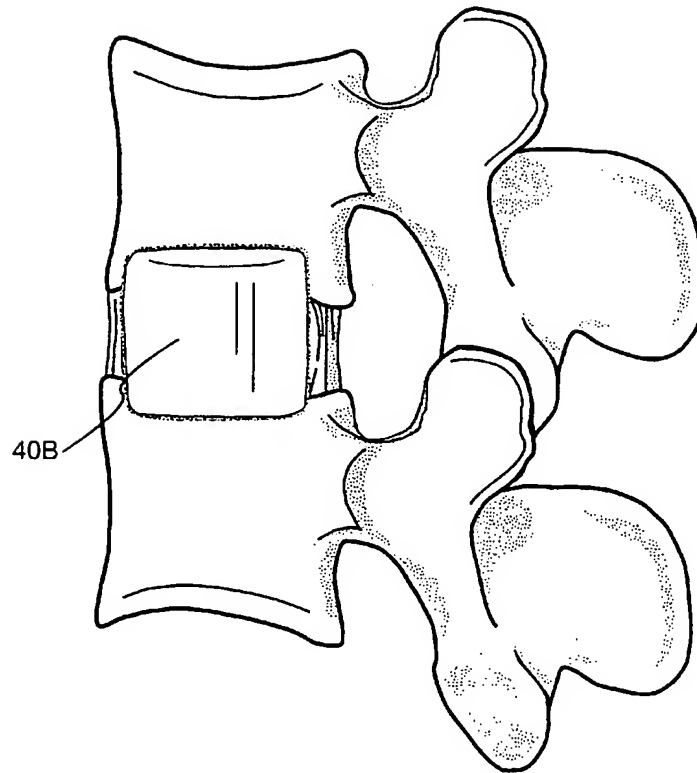


FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/12407

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/56, 17/70

US CL : 606/96: 623/17.12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/92, 96, 97; 623/17.12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,875,595 A (FRONING) 08 April 1975, whole document.	1, 2, 4, 5, 11-13, 15, 16, 21, 22, 25, 26, 41-46
Y	US 5,549,679 A (KUSLICH) 27 August 1996, whole document.	1, 2, 4, 5, 11-13, 15, 16, 21, 22, 25, 26, 41-46
Y	US 5,624,447 A (MYERS) 29 April 1997, whole document.	1, 7, 8, 41, 44, 45
Y	US 5,527,316 A (STONE et al.) 18 June 1996, whole document.	1, 7, 8, 44, 45

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"I"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

10 JULY 2000

Date of mailing of the international search report

05 SEP 2000

Name and mailing address of the ISA/US

Commissioner of Patents and Trademarks

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/12407

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,489,307 A (KUSLICH et al.) 06 February 1996, whole document.	41-46
Y	US 5,411,503 A (HOLLSTEIN et al.) 02 May 1995, whole document.	6, 20, 23, 43, 46
Y	US 5,013,317 A (COLE et al.) 07 May 1991, whole document.	6, 20, 23, 43, 46
Y	US 5,192,282 A (DRAENERT) 09 March 1993, whole document.	3, 42
Y	US 5,015,255 A (KUSLICH) 14 May 1991, whole document.	9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/12407

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1-9, 11-13, 15-23, 25-28 and 41-46, drawn to method, apparatus for fusing a spinal region utilizing guide tube, and drilling apparatus.

Group II, claims 10, 14, 24, 29-40 and 47-52, drawn to method, and apparatus for fusing a spinal region also including an inflatable member.

Group III, claim 53, drawn to a drilling tool.

Groups I, II and III, the inventions listed as these groups do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group II, the groupings as outlined above include mutually exclusive apparatus such as the inflatable member not recited by these groups, but included in Group II.

Group III is separately drawn to a drilling tool.